

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

This document relates to:

All Cases

MDL NO. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**MANUFACTURING DEFENDANTS' OPPOSITION TO PLAINTIFFS' EXECUTIVE
COMMITTEE'S EMERGENCY MOTION FOR LEAVE TO TAKE TRIAL
PRESERVATION DEPOSITION OF DAVID KESSLER**

Plaintiffs' request for leave to conduct a "trial preservation deposition" of Dr. David Kessler on an "emergency" basis, just seven days after unilaterally issuing the notice, is baseless. Dr. Kessler has not been disclosed as an expert, has not provided an expert report describing the scope of his opinions, and has not sat for a discovery deposition in any case pending in the MDL. Indeed, with the exception of the Track 3 action involving two Ohio counties and pharmacy defendants,¹ there is not a single case pending in the MDL for which discovery has even begun. And there is no case management schedule, let alone a scheduled trial date, for any other action pending in the MDL. Nor do Plaintiffs cite any authority permitting a trial preservation deposition of a *potential* expert, not yet retained or disclosed in an action. Rather, there is authority denying the Plaintiffs' exact request for a preservation deposition of Dr. Kessler in another matter. *See In re: Abilify (Aripiprazole) Products Liability Litigation*, No. 3:16-md-02734-MCR-GRJ (N.D. Fla. Jan. 5, 2021), ECF No. 1314 (attached as Ex. 1). If any of the MDL Plaintiffs have a need for an FDA expert at some time in the future, they are free to retain and disclose one in accordance with the case management schedule entered in their actions. Dr. Kessler may or may not be available

¹ See Revised Case Management Order for Track 3, *In re: National Prescription Opiate Litigation*, Case No. 17-md-2804, ECF No. 3595.

or willing to serve as an expert in future cases. But there is no emergency now that justifies an unprecedented and wholly premature deposition, in some set of hypothetical cases yet to be determined, in which no discovery has taken place.²

Dr. Kessler has been disclosed as an FDA/marketing expert in only two opioid cases—Track 1, which has been fully resolved against manufacturing defendants, and a state court action in New York. The New York plaintiffs (whose counsel overlap with MDL Plaintiffs' counsel on the PEC) noticed a “preservation” deposition in that action to take place January 13th. The manufacturing defendants moved for a protective order that will be heard by the court on January 15th. The pendency of that motion stays the deposition by operation of New York law. *See* N.Y. CPLR § 3103(b).

Nonetheless, in an apparent attempt to circumvent the stay effectuated by the motion for protective order in the New York action, Plaintiffs thereafter filed the instant motion here. Plaintiffs ask this Court to order the “trial testimony” of Dr. Kessler on an emergency basis less than a week from now, because they claim he might be ‘unavailable’ for all “forthcoming trials of MDL cases.” ECF No. 3594 at 1. The burden on, and prejudice to, Defendants to conduct a remote trial examination of Dr. Kessler now—before Dr. Kessler has even been disclosed in one of these

² To the extent the PEC intends to argue that Dr. Kessler should be deposed in connection with the remanded *City of San Francisco* and *City of Chicago* cases, those actions have been remanded by the JPML and are no longer pending in the MDL or subject to this Court’s jurisdiction. *See Manual for Complex Litigation, Fourth* § 20.133 (“After remand, the transferor court has exclusive jurisdiction, and further proceedings in the transferee court with respect to a remanded case are not authorized absent a new transfer order by the Panel.”); Response to Motion for Clarification, *In re: National Prescription Opiate Litigation*, Case No. 17-md-2804 (Track 2), ECF No. 3263 (“That said, the undersigned is quick to add that discovery disputes in the West Virginia remanded cases are no longer within this Court’s jurisdiction. Any further resolution of discovery disputes is within the purview of the transferor court.”) (citing *Manual for Complex Litigation, Fourth* § 20.133). In both cases, fact discovery is ongoing and no expert disclosures have been made or are even close to being due. Any deposition of Dr. Kessler in those actions would be inappropriate and premature, and Plaintiffs should not be allowed to circumvent the jurisdiction of the transferor courts.

unidentified MDL actions, let alone before discovery has finished or Plaintiffs have begun to put on their case—would be severe and unjustified.

Plaintiffs offer no justification for this extreme request, other than to say that Dr. Kessler was “recently [] asked to serve as the Co-Chair” to the Biden-Harris Transition COVID-19 Advisory Board and “*Dr. Kessler* has requested that the MDL Plaintiffs conduct a trial-preservation deposition” to preserve his testimony “regardless of his future availability.” ECF No. 3594 at 1-2 (emphasis added). In other words, Plaintiffs have not articulated whether, or why, Dr. Kessler will actually be ‘unavailable’ for whatever unscheduled trial Plaintiffs might someday identify him for—unless, perhaps, by ‘unavailability’ they mean getting this testimony now will allow Dr. Kessler to pursue whatever professional path he wants without having to worry about having to testify in-person in unknown, unscheduled, future MDL trials. Nor can Plaintiffs claim any true “emergency.” Dr. Kessler’s appointment to the Biden-Harris Transition COVID-19 Advisory Board was announced on November 9, 2020—*two months ago*—but Plaintiffs did not broach the notion of a trial preservation deposition in cases pending in the MDL until they filed their “emergency” motion just one week before the noticed deposition. Plaintiffs never sought to meet and confer about a trial preservation deposition in the MDL. This is not an “emergency” except of Plaintiffs’ own making.³

Indeed, Plaintiffs’ (and Dr. Kessler’s) ostensible urgency presumably is pretext for what is truly animating their efforts: Dr. Kessler believes he might be *unable* to serve as an expert or to testify at trial because he is anticipating becoming a federal government official once the Biden-Harris Transition has concluded. Dr. Kessler is reported to be one of two people being considered

³ Some of the same Plaintiffs lawyers in this case requested a similar trial preservation deposition in the New York opioid action on December 17, 2020. Plaintiffs have not provided any explanation for why they waited to make this request for MDL cases until January 6, 2020.

as FDA Commissioner in the new Administration. As this Court is well aware, it would be unprecedented and improper for a high-ranking federal official to serve simultaneously as an expert witness for state- or municipal-government plaintiffs in civil litigation. It would also run afoul of multiple federal regulations that, unsurprisingly, prohibit federal officials from engaging in such activities. None of the federal rules that govern deposition testimony for use at trial provides for an end-run around such patent conflicts. *See Abilify* Order (Ex. 1) (denying Plaintiffs' request for a preservation deposition of Dr. Kessler because Dr. Kessler's unavailability was speculative, and if Dr. Kessler was unavailable due to future status as a federal government employee, use of his preservation testimony at trial would be barred by government regulations).⁴

If Dr. Kessler's role is limited to duties for the Biden-Harris Transition, those are time-limited and should not make him unavailable to be retained and disclosed for future trials once COVID-19 is under sufficient control to allow trial to take place. If, on the other hand, Dr. Kessler is offered and chooses to take a new position that precludes him from testifying as a hired expert, MDL Plaintiffs can retain and disclose an available expert in any case where discovery becomes active. They cannot end run the rules by "preserving" his testimony for use in perpetuity now.

Plaintiffs state that they "seek leave solely to maintain the status *quo* by preserving Dr. Kessler's testimony now." ECF No. 3594 at 2. But the only status quo to preserve is one in which each individual MDL Plaintiff decides—at the appropriate time given the relevant case schedule—whether to disclose Dr. Kessler (or some other expert) in its individual action and, if so, makes

⁴ A California Superior Court for San Diego County has allowed a trial preservation deposition of Dr. Kessler to proceed. Unlike here, Dr. Kessler was retained and his opinions in that specific case were disclosed consistent with that Court's orders, where trial is scheduled on February 19, 2021. The Court stated it is "not making any ruling on whether the deposition will ever see the light of day," was "not making a ruling on the FDA issue," but "strongly urge[d] the plaintiffs to start doing some work on whether you might want to consider ***asking me to augment your expert witness list and put someone else in if Kessler's in charge of the FDA.***" Dec. 22, 2020 Hr'g Tr., *Hamilton v. Novartis Pharmaceuticals, Corp.*, Case No. 37-2013-00070440-CU-MM-CTL (Cal. Super. Ct.), at 5, 18-19 (attached as Ex. 2) (emphasis added).

him available for a deposition. It bears mention that in the only other opioid case in which expert discovery is ongoing—pending against the manufacturing defendants in California state court—Plaintiffs (represented by PEC counsel) opted not to disclose Dr. Kessler. The status quo is not that Dr. Kessler can testify now for purposes of any case pending in the MDL regardless of its procedural posture, simply because he was disclosed as an expert in long-since-resolved Track 1. Indeed, other Plaintiffs, like the People of the State of California, may opt not to retain or disclose Dr. Kessler even if he was available.

ARGUMENT

A. Plaintiffs Have Made No Showing That Dr. Kessler Will Be Unavailable.

Plaintiffs’ purported “unavailability” justification underlying their request for a trial preservation deposition for “forthcoming trials of MDL cases” cannot withstand scrutiny. ECF No. 3594 at 1. As a threshold matter, there is no *forthcoming* trial in the MDL. Indeed, with the exception of Track 3, there is not a single case pending in the MDL for which discovery is underway, let alone in which Dr. Kessler has been disclosed as an expert.

Nonetheless, Plaintiffs contend that Dr. Kessler will be too busy to testify at any MDL trial because he will be consumed by his duties on the Biden-Harris Transition COVID-19 Advisory Board. But Plaintiffs have failed to explain how long Dr. Kessler’s Biden-Harris Transition work might extend past the January 20 Inauguration. They imply that it will continue indefinitely, and that those COVID-19-related duties will consume all of his time for that indefinite period. But that is mere speculation, which is not enough to demonstrate unavailability. *See, e.g., United States v. Bell*, 2019 WL 3821296, at *2 (E.D. Mich. Aug. 14, 2019) (“There must be more than mere doubt that a material witness will be unavailable to warrant a pretrial deposition. . . . [C]ourts have denied pretrial depositions where a witness speculates that he may have work commitments in a foreign country during trial”).

That Dr. Kessler may choose to take a new position in the Biden Administration, which would preclude him from testifying for Plaintiffs in future MDL cases, does not make him unavailable and suddenly permit Plaintiffs to now preserve his testimony for any eventual trial. What is apparently motivating Plaintiffs' emergency request are the rumors that Dr. Kessler may have the opportunity to head the FDA once again in the Biden Administration. *See, e.g., Biden Closes in on Top Health Leaders as Pandemic Ravages U.S.*, Bloomberg (Dec. 2, 2020), <https://www.bloomberg.com/news/articles/2020-12-02/biden-closes-in-on-top-health-leaders-as-pandemic-ravages-u-s> ("Biden's choices to lead the Food and Drug Administration appear narrowed down to David Kessler . . . and Joshua Sharfstein") (attached as Ex. 3). But "[n]o officer or employee of the Food and Drug Administration or of any other office or establishment in the Department of Health and Human Services . . . shall give any testimony before any tribunal pertaining to any function of the Food and Drug Administration or with respect to any information acquired in the discharge of his official duties." 20 C.F.R. § 20.1. This provision would plainly preclude Dr. Kessler from testifying at any trial, as his presumptive opinions regarding whether defendants violated FDA standards of conduct relate to functions of the FDA and would involve knowledge he acquired in the course of his service as FDA Commissioner.

Because the very purpose of taking a trial preservation deposition would be to have that deposition serve as Dr. Kessler's trial testimony, using his "preserved" deposition testimony at a time when he is FDA Commissioner would put him in the impermissible position of serving as a trial expert (on videotape) while actively serving in a federal government position. *See 5 C.F.R. § 2635.702* ("An employee shall not use his public office for his own private gain, for the endorsement of any product, service or enterprise, or for the private gain of friends, relatives, or persons with whom the employee is affiliated in a nongovernmental capacity, including nonprofit

organizations of which the employee is an officer or member, and persons with whom the employee has or seeks employment or business relations.”); 5 C.F.R. § 2635.805 (“[E]mployee shall not serve, other than on behalf of the United States, as an expert witness, with or without compensation, in any proceeding before a court or agency of the United States in which the United States is a party or has a direct and substantial interest unless the employee’s participation is authorized by the agency under paragraph (c) of this section.”); 20 C.F.R. § 20.1 (“No officer or employee of the Food and Drug Administration or of any other office or establishment in the Department of Health and Human Services except as authorized by the Commissioner of Food and Drugs pursuant to this section or in the discharge of his official duties under the laws administered by the Food and Drug Administration, shall give any testimony before any tribunal pertaining to any function of the Food and Drug Administration or with respect to any information acquired in the discharge of his official duties.”). Dr. Kessler cannot provide testimony that would be prohibited if given live by preserving it on videotape in advance. As a result, no Court intervention is needed or appropriate at this time. In the event that Dr. Kessler is FDA Commissioner when Plaintiffs in a case pending in the MDL must disclose experts and make those experts available for trial, Plaintiffs can select and disclose an expert who will actually be able to do so.

There is no authority supporting such an unprecedented request, and Plaintiffs’ cited cases are materially distinguishable. In *Weist v. E.I. DuPont De Nemours & Co.*, 2009 WL 10681127 (W.D.N.Y. Aug. 27, 2009), not only did the plaintiffs serve the relevant *de bene esse* deposition notice more than a month before the intended deposition, they did so just days after President Obama had announced his intent to nominate the deponent to be Assistant Secretary for OSHA. *Id.* at *1. Further unlike here, discovery was already complete in the relevant actions in *Weist* at

the time the deposition was noticed. In *In re: NC Swine Farm Nuisance Litig.*, 2016 WL 3742135 (E.D.N.C. July 7, 2016), there was little doubt that the *de bene esse* deponent would be unavailable, as he had been “diagnosed with stage 4 colon cancer with liver metastases” and his ability to sit for a deposition was “temporary because his condition [was] terminal and his treatment palliative.” *Id.* at *1-2. And in both cases, unlike here, the experts had already been disclosed by the time the Court blessed the *de bene esse* depositions.

Another federal court overseeing non-opioids-related actions recently denied the plaintiffs’ motion for leave to depose Dr. Kessler, *in a case that was active and in which he had actually submitted an expert report*. In *In re: Abilify (Aripiprazole) Products Liability Litigation*, the plaintiffs sought a court order allowing them to take Dr. Kessler’s deposition “expeditiously” and “preserve his testimony in the event that he will be unavailable at trial.” Ex. 1 at 7 (internal quotation marks omitted). The plaintiffs argued that a trial preservation deposition was necessary because Dr. Kessler ““may later be unavailable due to scheduling conflicts[] or other agency related needs’ arising from his role as co-chair of President-Elect Biden’s COVID-19 Task Force or a ‘higher appointment’ within the administration.” *Id.* at 8. But the court rightly identified this as “untenable speculation”—and even if Dr. Kessler is nominated to lead the FDA, “there is no telling when that nomination will occur and how long it will take the Senate to act on the nomination.” *Id.* at 9-10. The court also underscored that there is no authority “for the proposition that regulations concerning the testimony of government employees do not apply to deposition testimony used at trial.” *Id.* at 10-11. At the very least, according to the court, the Housekeeping Statute (5 U.S.C. § 301), the FDA’s *Touhy* regulations (21 C.F.R. § 20.1(a)), and the prohibition on federal employees from “engag[ing] in outside employment or any other outside activity that conflicts with his official duties” (5 C.F.R. § 2635.802) would all apply to Dr. Kessler should he

become FDA Commissioner. But as the *Abilify* court explained, Plaintiffs “cannot circumvent these regulations by deposing Dr. Kessler now because that testimony can only be used at trial as if Dr. Kessler were testifying live, with all attendant circumstances.” Ex. 1 at 11 (citing Fed. R. Civ. P. 32(a)(1)(B)).

In sum, a trial preservation deposition “would not circumvent the pertinent regulations prohibiting [Dr. Kessler’s] trial testimony” and allow Dr. Kessler to testify at trial when he otherwise would not be permitted as a government employee; and, “[i]f Dr. Kessler is not a government employee, he should be available to testify at trial.” Ex. 1 at 12. But the Court need not even wade into this hypothetical now, because there is no case pending in the MDL in which discovery is active and in which a Plaintiff has sought to disclose Dr. Kessler, and there is no trial date in any case pending in the MDL set at all, let alone a trial date for which Dr. Kessler, if retained and disclosed, could already be deemed unavailable.

B. A Premature—And Tremendously Rushed—Trial Preservation Deposition Would Result In Extreme Prejudice To Manufacturer Defendants.

Allowing Plaintiffs’ gambit to proceed here would significantly prejudice Defendants and waste substantial resources in the middle of a pandemic and without any imminent trial date on the calendar. The whole premise of Plaintiffs’ motion presumes that Plaintiffs are entitled to have Dr. Kessler serve as an expert in any future case pending in the MDL that becomes active. There is no authority for such a novel claim. Nor does Dr. Kessler have a right to be paid to give trial testimony now in cases where discovery has not even begun to proceed, simply because it would be more convenient for him now than next year or the year after. Having a busy schedule does not render a witness unavailable under the Federal Rules. And given the absence of ongoing, active cases in the MDL, any MDL Plaintiff will have ample time to obtain and designate an expert to testify on similar topics, should they deem it necessary. *See Holmes v. Merck & Co.*, 2006 WL

1744300, at *2-3 (D. Nev. June 22, 2006) (“[B]ecause a retained expert witness usually has no involvement with the case other than his willingness to review the case and testify as an expert, a party is likely to have the ability to select an expert witness who will or should be available to testify at trial.”).

Plaintiffs’ insistence on a rushed January 13 date in the middle of a COVID-19 spike also does not allow Defendants adequate time to prepare for Dr. Kessler’s trial examination. *See, e.g.*, *Tierney v. Omnicom Group, Inc.*, 2007 WL 2766680, *3 (S.D.N.Y. Sept. 21, 2007) (“[S]hould Plaintiff’s deposition be taken in the next two weeks, it would result in prejudice to Defendant and the expenditure of unnecessary time and expense.”); *see also* Fed. R. Civ. P. 30(b)(1) (“A party who wants to depose a person by oral questions must give *reasonable* written notice to every other party.” (emphasis added)). And it would foreclose Defendants’ ability to cross-examine Dr. Kessler as they would at trial, after case-specific discovery has been completed, with the benefit of expert disclosures and reports consistent with Court orders, and with knowledge of issues resolved between now and trial, Plaintiffs’ opening statements, the Court’s evidentiary rulings, and other trial testimony.

Moreover, Plaintiffs’ assertion that “[n]one of the opinions offered by Dr. Kessler” in his Track 1 and New York “expert report[s] or deposition[s] were specific to the plaintiffs in those cases” is irrelevant. ECF No. 3594 at 1. This trial preservation deposition is not related to Track 1—Track 1 has concluded. And the parties involved in the New York litigation are currently briefing the same issue before that court. To date, Dr. Kessler has not been disclosed or submitted an expert report in any other action.⁵ Defendants have not deposed Dr. Kessler in any other action,

⁵ The lack of report in and of itself should be enough to bar plaintiffs from deposing Dr. Kessler. A discovery deposition of him could not be taken now in the MDL because he has not issued an expert report in an active MDL case. Fed. R. Civ. P. 26(b)(4)(A) (“A party may depose any person who has been identified as an expert whose opinions may be presented at trial. If Rule 26(a)(2)(B) requires a report from the expert, the deposition

which they will have the right to do *if* he is disclosed. *See, e.g., In re: Syngenta AG MIR 162 Corn Litig.*, 2020 WL 7316100, at *3, n.2 (D. Kan. Dec. 11, 2020) (explaining that “Rule 26 gives Syngenta the right to depose any designated expert witness” and that “[t]he only natural and reasonable reading of that language is that the party may depose the witness *after* the expert designation”) (emphasis in original). Discovery in these other actions might prompt different opinions from Dr. Kessler. It will without a doubt prompt different cross examination from Defendants. As just one example, in the New York consolidated litigation, the court has recognized manufacturing defendants’ right to discovery from the New York Bureau of Narcotic Enforcement (“BNE”). Those BNE documents are relevant to the New York plaintiffs’ allegations (and Dr. Kessler’s opinion) that the defendants in that action “caused the ‘opioid epidemic’ and created, maintained or joined in the drug trafficking, diversion and drug overdoses.” Jan. 2, 2020 Order, *In re Opioid Litigation*, Index No. 400000/2017 (N.Y. Sup. Ct.), NYSCEF No. 2349 at 2 (attached as Ex. 4). The State of New York, however, has not produced those documents pending appeal of the court orders requiring the State to do so—and a premature deposition of Dr. Kessler in that case would deprive defendants of the right to cross examine him with those documents in hand. Similar types of documents likely exist in other states and across other jurisdictions that are plaintiffs in the MDL—but those and other relevant documents have not yet been produced to because those cases are not active. If a deposition were to proceed on January 13, Defendants would not have a full record with which to cross examine Dr. Kessler about any opinions he might give, including concerning the critical issue of causation.⁶

may be conducted only after the report is provided.”) (emphasis added). If a discovery deposition cannot now be taken, then certainly trial testimony cannot be.

⁶ One of the cases Plaintiffs rely on, *McDermott v. Liberty Maritime, Corp.*, No. 08-cv-1503, 2010 U.S. Dist. LEXIS 96992 (E.D.N.Y. Sept. 16, 2010), actually proves Defendants’ point. In *McDermott*, the court emphasized that “Fed. R. Civ. P. 26(b)(4) allows a party to depose any person who has been identified as an expert and whose opinions may be presented at trial.” *Id.* at *1. The court found that it would be “unfair to force Defendants to

Furthermore, Plaintiffs' assertion that Dr. Kessler's opinions are not specific to individual plaintiffs is plain wrong. *See* ECF No. 3594 at 1. The crux of his opinion is that allegedly misleading marketing materials influenced the practice of medicine *in a plaintiff's jurisdiction*. To reach that opinion, Dr. Kessler relies on jurisdiction specific evidence to purportedly show what marketing reached what doctors in a plaintiff's jurisdiction. *See* Kessler NY Report ¶ 133 ("For example one New York call note states"); *id.* ¶ 162 ("For example, a New York call note from 2003 states"); *id.* ¶ 168 ("For example, one New York call note from 2004 states"); Jan. 17, 2020 Kessler NY Dep. Tr. at 218:13-14 (identifying specific doctors that were allegedly misled by marketing in New York); *see also* Kessler MDL Track 1 Report ¶ 306 ("For example, one Ohio call"); *id.* ¶ 337 ("An Ohio sales note from 2004 stated"); *id.* ¶ 338 ("Ohio call notes from 1998 stated"); *id.* ¶ 445.1 ("An Ohio call note from June 2009 reported"). Probing the connection between the marketing materials and the prescribing community in a plaintiff's jurisdiction is the cardinal issue for Defendants examination of Dr. Kessler.

* * *

Plaintiffs sprung this motion on Defendants just *one week* before Dr. Kessler's requested trial preservation deposition date of January 13, notwithstanding the public announcement of Dr. Kessler's appointment to the Biden-Harris Transition COVID-19 Advisory Board came *two months ago*. This is an "emergency" of Plaintiffs' own making. Defendants should not be so prejudiced, and the Court should not condone such gamesmanship.

conduct trial examination of Plaintiff's experts either during or immediately after the deposition without the benefit of conducting a proper discovery deposition" because "Defendants have a right to prepare their cross-examination questions in accordance with standard trial practice, to consult their own experts about the testimony provided from the depositions, and to prepare a trial strategy based on the information supplied by Plaintiff's experts." *Id.* Under the instant circumstances, however, allowing a trial preservation deposition of Kessler to proceed would deprive Defendants of all such rights.

CONCLUSION

The Court should deny Plaintiffs' request to take a "preservation" deposition of Dr. Kessler.

Dated: January 8, 2021

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CERTIFICATE OF SERVICE

I hereby certify that on January 8, 2021, a copy of the foregoing Opposition to plaintiffs' executive committee's emergency motion for leave to take trial preservation deposition of David Kessler was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

By: /s/ Donna M. Welch
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